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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,014	03/06/2006	Allan Tanghoj	P70598US0	8511
136 7590 06/26/2007 JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			EXAMINER TREYGER, ILYA Y	
			ART UNIT 3709	PAPER NUMBER
			MAIL DATE 06/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,014

Applicant(s)

TANGHOJ, ALLAN

Examiner

Ilya Y. Treyger

Art Unit

3709

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/07/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claims 1-21 of US Application 10/517014, filed 11/28/2003, are presented for examination.

Claim Rejections - 35 USC § 102

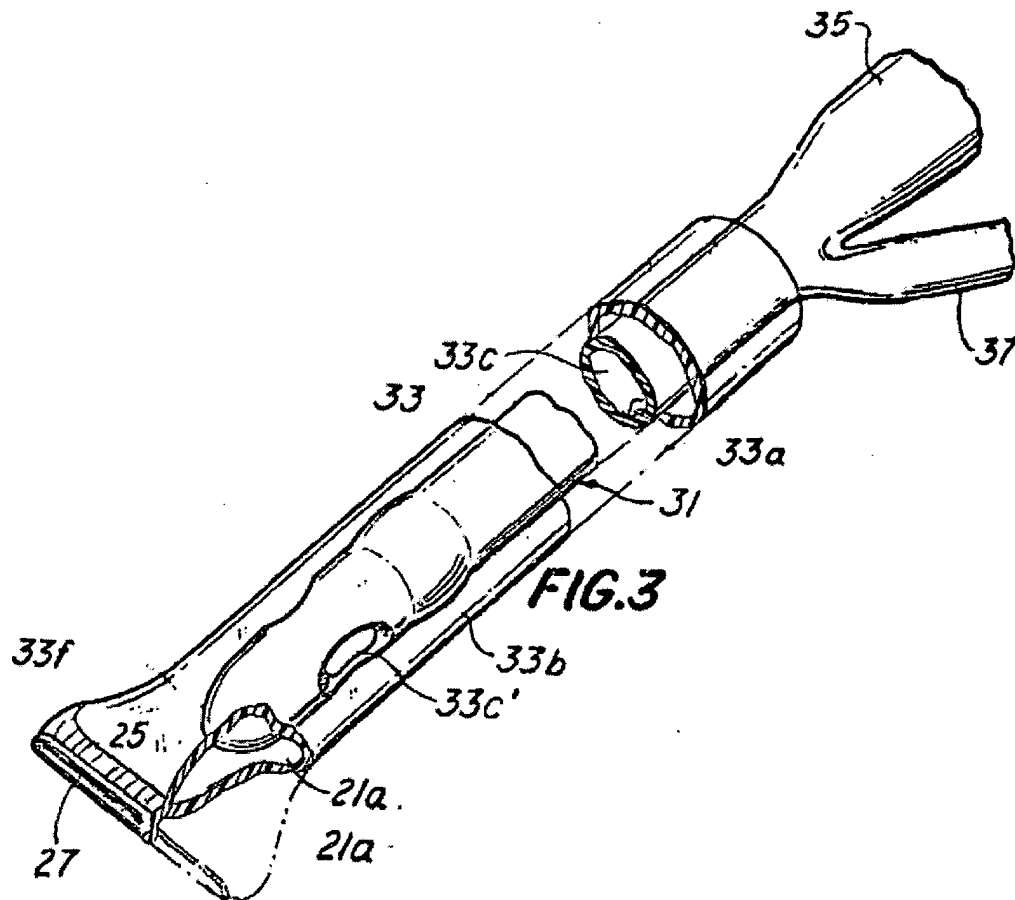
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 4, 10, 14, 16, 17 and 18 are rejected under 35 U.S.C. 102 (b) as being anticipated by **Robert W. Juster et al. (US 3,934,721)**.

1. **In Re claim 1, Juster** discloses a catheter with a conduit for draining body fluid from at least one inlet opening in the proximal, insertable, end of the catheter to at least one outlet opening, said catheter comprising first and second parts, wherein the first part forms the proximal end, and the second part forms the distal end, the first and second parts having different cross- sectional size and/or shape and being joined in a fixed connection, and the first part is at least partly encapsulated in a sleeve to leave at least a portion of the second part of the catheter uncovered by the sleeve, characterized in that the sleeve is attached to the catheter reducing the risk that the sleeve accidentally falls off when handling the catheter prior to use (See Col. 1, ln. 65-68; Col. 2, ln. 13-15; Fig. 3).



2. **In Re claim 2, Juster** discloses a catheter, wherein the sleeve is detachably attached to the outer surface of the catheter (See Fig. 3).
3. **In Re claim 3, Juster** discloses a catheter, wherein the sleeve forms at least a part of a liquid tight encapsulation of the first part (See Fig. 3).
4. **In Re claim 4, Juster** discloses a catheter, wherein the first part is entirely encapsulated by the sleeve (See Fig. 3).
5. **In Re claim 10, Juster** discloses a catheter, wherein the first and second parts are made in one piece (Fig. 3).

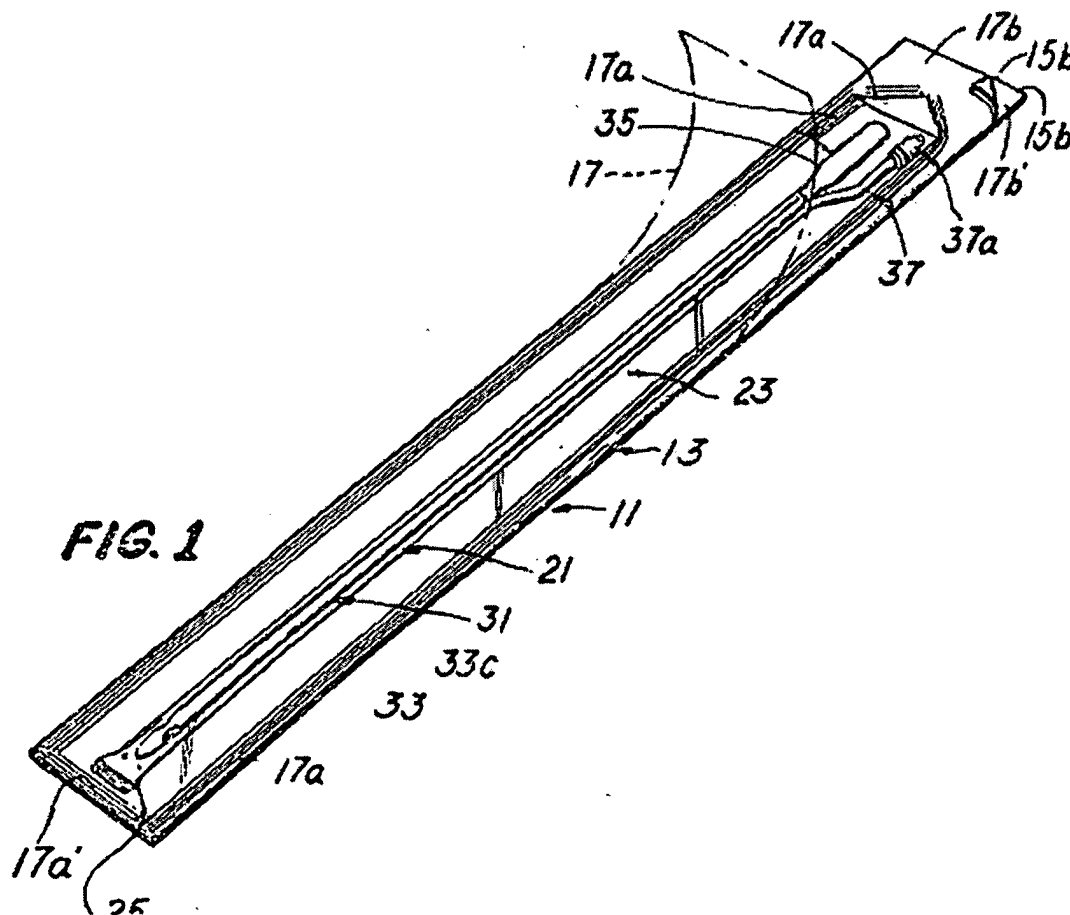
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6. **In Re claim 11, Juster** discloses a catheter, wherein the second part is made with a higher bending moment than the first part (See Fig. 3).

7. **In Re claim 14, Juster** discloses a catheter, wherein the second part comprises connection means for connecting collecting means for collection of the body fluid (See Col. 2, ln. 13-15; Fig. 3, c. 35, 37).

8. **In Re claim 16, Juster** discloses a catheter, wherein the sleeve is made from a dimensionally stable material (See Col. 2, ln. 25-26).

9. **In Re claim 17, Juster** discloses a catheter, wherein the sleeve forms part of a package for encapsulation of the first and the second parts in individual compartments (See Fig. 1).



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10. In Re claim 18, **Juster** discloses a catheter, wherein the sleeve or the first or the second part is made from a thermoplastic material (See Col. 2, ln. 52-53).

Claim 21 is rejected under **35 U.S.C. 102 (b)** as being anticipated by **Robert W. Juster et al. (US 3,934,721)**.

Juster discloses a sleeve for a catheter with inlet openings in its insertable end, said sleeve forming an oblong body with a cavity for the catheter and an opening for inserting the catheter into the cavity, characterised in that the cavity forms a cap portion covering the inlet openings of the catheter when the catheter is arranged in the cavity (See Col. 1, ln. 65; Col. 2, ln. 60-62; Fig. 1 and 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, 7, 8, 9, 12, and 13 are rejected under **35 U.S.C. 103(a)** as being unpatentable over **Robert W. Juster et al. (US 3,934,721)** in view of **Elio D'Amico (US 5,429,613)**.

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1. **In Re claim 5, Juster** discloses a catheter discussed above, but does not expressly disclose a catheter, wherein the at least one inlet opening is sealed by a detachable closure.

D'Amico teaches that it is known to seal inlet opening of invasion device by a detachable closure (See Col. 5, ln. 6-12).

Please note that injection assembly and catheter both belong to invasion devices.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a catheter of **Juster** with the inlet opening sealed by a detachable closure, as taught by **D'Amico** because such modification would provide sterility during the transportation.

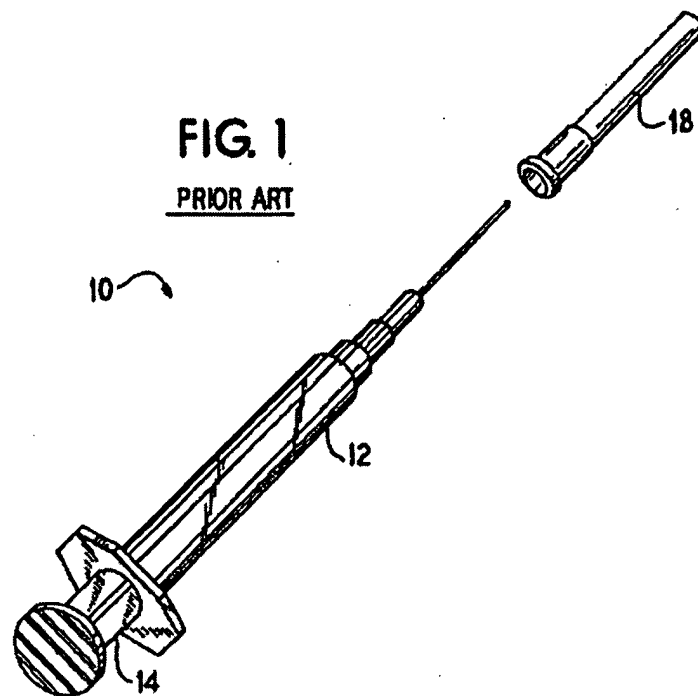
2. **In Re claim 6, Juster** discloses a catheter, wherein the closure forms part of the sleeve (See Fig. 3, c. 27).

3. **In Re claim 7, D'Amico** discloses an invasion device, wherein the at least one outlet opening is sealed by a detachable closure (See Col. 5, ln. 6-12).

Please note that injection assembly and catheter both belong to invasion devices.

4. **In Re claim 8, D'Amico** discloses an invasion device, wherein the first and second parts are made from different materials (See Fig. 1).

Please note that injection assembly and catheter both belong to invasion devices.



5. In Re claim 9, Juster discloses the claimed invention except for a catheter, wherein the length of the second part constitutes at least 1/3 of the total length of the catheter.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the length of the second part to be constitutes at least 1/3 of the total length of the catheter, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (MPEP 2144.05 (II-B)). *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

6. In Re claim 12, Juster discloses the claimed invention except for a catheter, wherein the second part is made with a higher surface friction than the first part.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the second part with a higher surface friction than the first part, since it has been held that the provision of adjustability, where needed, involves routine skill in the art (**MPEP 2144 (V-D)**). In re Stevens, *101 USPQ 284 (CCPA 1954)*.

7. **In Re claim 13, Juster** discloses the claimed invention except for a catheter, wherein the second part in a radial direction extends 2-10 times the radial size of the first part.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to the second part in a radial direction extends 2-10 times the radial size of the first part, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art **MPEP 2144.05 (II-A)**. *In re Aller*, 105 USPQ 233.

Claims 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Robert W. Juster et al. (US 3,934,721)** in view of **Richard N. Starke et al. (US 5,147,341)**.

1. **In Re claim 15, Juster** discloses a catheter discussed above, but does not expressly disclose a catheter, wherein the outlet opening is in fluid connection with a receptacle for collection of the body fluid.

Starke teaches that it is known the outlet opening is in fluid connection with a receptacle for collection of the body fluid (See Col. 2, ln. 51-55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a catheter of **Starke** with the outlet opening is in fluid connection with a receptacle for collection of the body fluid, as taught by **Starke** because such modification would provide a urine collection.

2. **In Re claim 19, Juster** discloses the claimed invention except for a catheter, wherein sterility is maintainable within the sleeve during direct contact with the second part.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide sterility maintainable within the sleeve during direct contact with the second part, since it was known in the art that the maintainable sterility of the parts is a mandatory requirement for any invasion device.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Robert W. Juster et al. (US 3,934,721)** in view of **Yeongchi Wu et al. (US 4,204,527)**.

Juster discloses a catheter discussed above, but does not expressly disclose a catheter made for draining urine from a bladder or urinary tract.

Wu teaches that it is known to use a catheter made for draining urine from a bladder or urinary tract (See Abstract, ln. 4-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a catheter of **Juster** with a catheter made for draining urine from a bladder or urinary tract, as taught by **Wu** because such modification would provide draining urine from a bladder or urinary tract.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,019,102 disclose the urinary catheter. US 4,929,232 disclose the invasion device. US 2,371,086 disclose the invasion assembly. US 5,087,252 disclose urinary catheter.

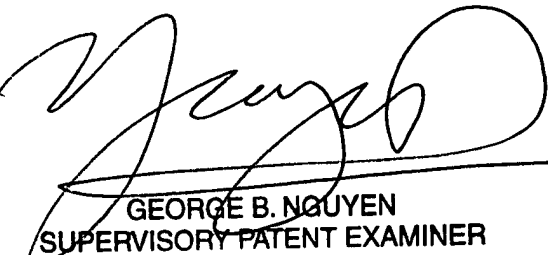
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ilya Y. Treyger whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Nguyen can be reached on 571-270-1431. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Ilya Y. Treyger
Examiner
3709



GEORGE B. NGUYEN
SUPERVISORY PATENT EXAMINER